CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13104	**Date: March 13, 2025**
	Change Request 13966

SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

I. SUMMARY OF CHANGES: The purpose of this Recurring Update Notification (RUN) is to provide instructions for the quarterly update to the CLFS. This RUN applies to chapter 16, section 20.

EFFECTIVE DATE: April 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 7, 2025

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 13104	Date: March 12, 2025	Change Request: 13966

SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

EFFECTIVE DATE: April 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 7, 2025

I. SUMMARY OF CHANGES: The purpose of this Recurring Update Notification (RUN) is to provide instructions for the quarterly update to the CLFS. This RUN applies to chapter 16, section 20.

II. GENERAL INFORMATION

A. Background: The purpose of this RUN is to provide instructions for the quarterly update to the CLFS. This RUN applies to chapter 16, section 20.

B. Policy: Clinical Laboratory Fee Schedule (CLFS)

Section 1834A of the Act, as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. The CLFS final rule "Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule" (CMS-1621-F) was published in the Federal Register on June 23, 2016. The CLFS final rule implemented section 1834A of the Act. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) was from January 1, 2019, through June 30, 2019.

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests

On September 26, 2024, Section 221 of the Continuing Appropriations and Extensions Act, 2025 was passed and delayed data reporting requirements for CDLTs that are not advanced diagnostic laboratory tests, and it also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation. Please see below for the following changes:

- The next data reporting period will be from January 1, 2026 – March 31, 2026, and based on the original data collection period of January 1, 2019, through June 30, 2019.
- A 0% payment reduction will be applied for Calendar Year (CY) 2025 so that a CDLT that is not an ADLT may not be reduced compared to the payment amount for that test in CY 2024, and for CYs 2026-2028 payment may not be reduced by more than 15-percent per year compared to the payment amount established for a test the preceding year.
- After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2029, 2032, etc.).

Advanced Diagnostic Laboratory Tests (ADLTs)

- Please refer to the following CMS website for additional information regarding these tests: https://www.cms.gov/medicare/clinical-laboratory-fee-schedule/adlt-information

New Codes Effective April 1, 2025

The listed new code has been added to the national HCPCS file with an effective date of April 1, 2025 and does not need to be manually added to the HCPCS files by the MACs. However, this new code is contractor-priced (where applicable) until it is addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July 2025, as it was received after the 2024 public meeting.

- CPT Code: G0567

  Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, screening, amplified probe technique

  Short Descriptor: Screening Hep C detect

  TOS: 5

Proprietary Laboratory Analysis (PLAs) and Additional New Codes

Please see table attached to the Transmittal entitled **"CY2025 CLFS Quarter 2 Updates,"** Tab "**New Codes Effective 04-1-25.**" The listed new codes were added to the national Healthcare Common Procedure Coding System (HCPCS) file with an effective date of April 1, 2025 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act Subsection (§) 1833(h)(8), § 1834A(c) and § 1834(A)(f). MACs shall only price PLA codes for laboratories within their jurisdiction. The table includes the laboratory, long descriptor, short descriptor, and Type of Service (TOS) of each new code.

Deleted Codes Effective April 1, 2025

Please see table attached to the Transmittal entitled "**CY2025 CLFS Quarter 2 Updates,**" Tab "**Deleted Codes Effective 04-1-25.**" The listed codes are being deleted with a delete date of April 1, 2025.

The table includes the code, long descriptor and the delete date of the code.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13966.1	Contractors shall be aware of any new ADLT codes, and/or (Common Procedural Terminology) CPT/HCPCS codes (including their TOS designation(s) and Effective date), and/or any deleted/terminated codes as	X	X						X	

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	applicable listed in this change request and shall update their systems as necessary to accept/delete/terminate them.									
13966.1.1	In instances where Medicare covered CLFS procedure codes do not yet appear on the quarterly CLFS file or the quarterly Integrated Outpatient Code Editor (IOCE) update, contractors shall locally price the codes until they appear with a rate on the CLFS file and/or, for Part A claims, the IOCE.	X	X							
13966.2	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X	X							
13966.3	Contractors shall use the cloud fee schedule to determine the payment limit for claims for separately payable Medicare Part B laboratory tests processed or reprocessed on or after April 1, 2025.	X	X							
13966.4	The A/B MACs Part A shall retrieve the CY 2025 Clinical Laboratory Fee Schedule from the CMS cloud on or after April 1, 2025.	X								Hybrid Cloud Data Center (HCDC)

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for

distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part A, A/B MAC Part B

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information:N/A

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

New Codes Effective April 1, 2025

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of April 1, 2025 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

MACs shall only price PLA codes for laboratories within their jurisdiction.

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
NeXGenTM Fungal/AFB NGS Assay, Eurofins Viracor, LLC, Eurofins Viracor, LLC	0531U	Infectious disease (acid-fast bacteria and invasive fungi), DNA (673 organisms), next-generation sequencing, plasma	NFCT DS AFB&INV FNG 673ORGS	5	4/1/2025
Rapid Genome Sequencing Test, University of California San Francisco Genomic Medicine Laboratory, University of California San Francisco	0532U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome and mitochondrial DNA sequencing for single- nucleotide variants, insertions/deletions, copy number variations, peripheral blood, buffy coat, saliva, buccal or tissue sample, results reported as positive or negative	RARE DS WHLGEN&MITOCHD RL DNA	5	4/1/2025
UCSF Pharmacogenomics Panel, University of California San Francisco Genomic Medicine Laboratory, University of California San Francisco	0533U	Drug metabolism (adverse drug reactions and drug response), genotyping of 16 genes (ie, ABCG2, CYP2B6, CYP2C9, CYP2C19, CYP2C, CYP2D6, CYP3A5, CYP4F2, DPYD, G6PD, GGCX, NUDT15, SLCO1B1, TPMT, UGT1A1, VKORC1), reported as metabolizer status and transporter function	RX METAB ADVRS GNOTYP 16GENS	5	4/1/2025
PROSTOXTM ultra, MiraDx, Inc, MiraDx, Inc	0534U	Oncology (prostate), microRNA, single-nucleotide polymorphisms (SNPs) analysis by RT-PCR of 32 variants, using buccal swab, algorithm reported as a risk score	ONC PRST8 MIRNA SNP 32 VRNT	5	4/1/2025
PFAS Testing & PFASure®FT, National Medical Services (NMS Labs), Laboratory Developed Test	0535U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative	PFAS LC-MS/MS PLSM/SRM QUAN	5	4/1/2025
Prenatal Detect RhD, Devyser Genomic Laboratories, Devyser AB	0536U	Red blood cell antigen (fetal RhD), PCR analysis of exon 4 of RHD gene and housekeeping control gene GAPDH from whole blood in pregnant individuals at 10+ weeks gestation known to be RhD negative, reported as fetal RhD status	RBCAG FTL RHD PCR ALYS EXON4	5	4/1/2025
ShieldTM, Guardant Health, Inc, Guardant Health, Inc	0537U	Oncology (colorectal cancer), analysis of cell-free DNA for epigenomic patterns, next-generation sequencing, >2500 differentially methylated regions (DMRs), plasma, algorithm reported as positive or negative	ONC CLRCT CA CFDNA >2500 DMR	5	4/1/2025
PredicineATLASTM Assay, Predicine Inc, Predicine Inc	0538U	Oncology (solid tumor), next- generation targeted sequencing analysis, formalin-fixed paraffin- embedded (FFPE) tumor tissue, DNA analysis of 600 genes, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and copy number alterations, microsatellite instability, tumor mutation burden, reported as actionable variant	ONC SOL TUM NGTS FFPE 600GEN	5	4/1/2025
PredicineCARETM Assay, Predicine Inc, Predicine Inc	0539U	Oncology (solid tumor), cell- free circulating tumor DNA (ctDNA), 152 genes, next-generation sequencing, interrogation for single- nucleotide variants, insertions/deletions, gene rearrangements, copy number alterations, and microsatellite instability, using whole-blood samples, mutations with clinical actionability reported as actionable variant	ONC SOL TUMOR CFCTDNA 152GEN	5	4/1/2025
AlloSure®, CareDx® Laboratory, CareDx®, Inc	0540U	Transplantation medicine, quantification of donor- derived cell-free DNA using next-generation sequencing analysis of plasma, reported as percentage of donor- derived cell free DNA to determine probability of rejection	TRNSPLJ MED QUAN DD-CFDNA	5	4/1/2025
HDL Reverse Cholesterol Transport Panel with pCAD Score, Quest Diagnostics®, Quest Diagnostics®	0541U	Cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), serum, algorithm reported as prediction of coronary artery disease (pCAD) score	CV DS HDL RCT CEC LC-MS/MS 5	5	4/1/2025
myOLARISTM-KTdx, Olaris®, Inc, Olaris®, Inc	0542U	Nephrology (renal transplant), urine, nuclear magnetic resonance (NMR) spectroscopy measurement of 84 urinary metabolites, combined with patient data, quantification of BK virus (human polyomavirus 1) using real-time PCR and serum creatinine, algorithm reported as a probability score for allograft injury status	NEFRO RENAL TRNSPL UR NMR 84	5	4/1/2025
TruSightTM Oncology Comprehensive, Illumina, Inc	0543U	Oncology (solid tumor), next- generation sequencing of DNA from formalin-fixed paraffin-embedded (FFPE) tissue of 517 genes, interrogation for single- nucleotide variants, multi-nucleotide variants, insertions and deletions from DNA, fusions in 24 genes and splice variants in 1 gene from RNA, and tumor mutation burden	ONC SOL TUM NGS DNA 517 GENS	5	4/1/2025
VitaGraftTM Kidney 2.0, Oncocyte Corporation, Oncocyte Corporation	0544U	Nephrology (transplant monitoring), 48 variants by digital PCR, using cell-free DNA from plasma, donor-derived cell-free DNA, percentage reported as risk for rejection	NEFRO TRNSP MNTR 48VRNT DPCR	5	4/1/2025
AChR Live Cell-Based Assay, Neurocode USA, Inc, Neurocode USA, Inc	0545U	Acetylcholine receptor (AChR), antibody identification by immunofluorescence, using live cells, reported as positive or negative	ACHR ANTB ID IMFLUOR LIVECLL	5	4/1/2025
LRP4 Cell-Based Assay, Neurocode USA, Inc, Neurocode USA, Inc	0546U	Low-density lipoprotein receptor-related protein 4 (LRP4), antibody identification by immunofluorescence, using live cells, reported as positive or negative	LDNS LRP4 ANTB IMFLR LIVECLL	5	4/1/2025
Neurofilament Light Blood Test, Neurocode USA, Inc, Fujirebio Diagnostics, Inc	0547U	Neurofilament light chain (NfL), chemiluminescent enzyme immunoassay, plasma, quantitative	NEURFLMNT LT CHN CLEIA PLSM	5	4/1/2025

Glial Fibrillary Acidic Protein Blood Test, Neurocode USA, Inc, Fujirebio Diagnostics, Inc	0548U	Glial fibrillary acidic protein (GFAP), chemiluminescent enzyme immunoassay, using plasma	GFAP CLEIA PLASMA	5	4/1/2025
Bladder CARETM, Pangea Laboratory LLC, Pangea Laboratory LLC	0549U	Oncology (urothelial), DNA, quantitative methylated real- time PCR of TRNA-Cys, SIM2, and NKX1-1, using urine, diagnostic algorithm reported as a probability index for bladder cancer and/or upper tract urothelial carcinoma (UTUC)	ONC URTHL DNA MTHYLTD RT PCR	5	4/1/2025
ClarityDx Prostate, Protean BioDiagnostics, Protean BioDiagnostics	0550U	Oncology (prostate), enzyme- linked immunosorbent assays (ELISA) for total prostate-specific antigen (PSA) and free PSA, serum, combined with age, previous negative prostate biopsy status, digital rectal examination findings, prostate volume, and image and data reporting of the prostate, algorithm reported as a risk score for the presence of high-grade prostate cancer	ONC PRST8 ELISA TOT&FREE PSA	5	4/1/2025
LucentAD p-Tau 217, Quanterix Corporation, Quanterix Corporation	0551U	Tau, phosphorylated, pTau217, by single-molecule array (ultrasensitive digital protein detection), using plasma	TP PTAU217 ULT DGT PRTN DETJ	5	4/1/2025

Deleted Codes Effective April 1, 2025		
The following codes are being deleted with a deletion date of April 1, 2025.		
CPT Code	**Short Descriptor**	**Delete Date**
0066U	Pamg-1 ia cervico-vag fluid	4/1/2025
0078U	Pain mgt opi use gnotyp pnl	4/1/2025
81433	Hrdtry brst ca-rlatd dsordrs	4/1/2025
81436	Hereditary colon ca dsordrs	4/1/2025
81438	Heredtry nurondcrn tum dsrdr	4/1/2025
86327	Immunoelectrophoresis assay	4/1/2025